

Sheet 1 of 6

Form PTO-1449		Do	ocket No.: 3707	0/207071	A	oplication No. 09/932	,503 P	
INFORMATION DISCLOSURE CITATION		Ar	Applicant: Tulin Morcol, et al.					
	APPLICATION	Fil	ing Date:		G	oup Art Unit	<u>m</u>	7
(Use several	sheets if necessary)		Augu	st 17, 2001	16	345		_
			U.S. PATE	NT DOCUMENTS			පි	2
Examiner Initial	Document Num	ber	Date	Name	Class	Subclass	Translat 2900	ior
RZ	3,925,545		12/09/75	Relyveld			<u> 8</u>	
4	4,016,252		04/05/97	Relyveld		-		
	4,350,686		09/21/82	Relyveld, et al.			ļ	
	4,500,512		02/19/85	Barme				
	4,552,756		11/12/85	Relyveld, et al.				_
	4,963,526		10/16/90	Ecanow				
	5,110,606		05/05/92	Geyer, et. al			_	
	5,178,882		01/12/93	Kossovsky et al.				
	5,219,577		06/15/93	Kossovsky et al.			<u> </u>	
	5,306,508		04/26/94	Kossovsky et al.			<u> </u>	
	5,334,394		08/02/94	Kossovsky et al.			<u> </u>	
	5,364,838		11/15/94	Rubsamen			J	
	5,428,066		06/27/95	Larner, et al.				
	5,460,830		10/24/95	Kossovsky et al.				
	5,460,831		10/24/95	Kossovsky et al.				
	5,462,750		10/31/95	Kossovsky et al.	—			
	5,462,751		10/31/95	Kossovsky et al.	T			
	5,464,634		11/07/95	Kossovsky et al.				
	5,506,203		04/09/96	Backstrom et al.	<u> </u>			
	5,549,973		08/27/96	Majetich et al.				
	5,580,859		12/03/96	Felgner et al.				
	5,593,875		01/14/97	Wurm, et al.				
	5,595,762		1/21/97	Derrieu et al.				
	5,618,800		04/08/97	Kabra, et al.				
	5,620,896		04/15/97	Herrmann et al.				
	5,629,021		05/13/97	Wright		-		
	5,641,515		06/24/97	Ramtoola	\ -			
	5,648,097		7/15/97	Nuwayser				
	5,665,382		09/09/97	Grinstaff, et al.				
	5,695,617		12/09/97	Gravier et al.				
	5,747,001		05/05/98	Wiedmann et al.	T			
- 	5,785,975		07/28/98	Parikh		-		_
	5,824,638		10/20/98	Burnside, et al.		-		
	5,827,822		10/27/98	Floc'h et al.				
1 1	5,843,887		12/01/98	Petit, et al.		-	1	_
 	5,858,398		01/12/99	Cho			1	
	5,866,553		02/02/99	Donnelly et al.			1	
J	5,891,420	_	04/06/99	Cutie				
RZ	5,898,028	\neg	04/27/99	Jensen et al.				
XAMINER: Initia		wheth		on is in conformance with	MPEP 6 6	09; Draw line thr	ough citatio	on if

1299273

Form PTO-1449 INFORMATION DISCLOSURE CITATION IN AN APPLICATION		Docket No.: 37070/207071			Application No. 09/932,503			
		Applicant: Tulin	Morcol, et al.		, C			
	APPLICATION sheets if necessary)	Filing Date: Augu	ust 17, 2001	Gro 164	up Art Unit 15	₹ (
RZ	5,902,789	05/11/99	Stolz			7 !		
	5,985,312	11/16/99	Jacob, et al.			200		
	6,017,545	01/25/00	Modi		_ 8			
	6,156,348	2/05/00	Santos, et al.		- 1	\$		
	6,183,803	02/06/01	Morcoletal		- 3	3		
4	6,187,335	02/13/01	Brey, et al.					
ř?	6,355,271	03/12/02	Bell, et al.					
		NON-US PA	TENT DOCUMEN	TS				
caminer	Document Number		Country	Class	Subclass	Translation		
itial								
R 2	WO 90/11092	10/04/90				<u> </u>		
1	WO 93/17706	09/16/93	}		_			
	WO 93/24640	12/09/93		_	_			
	WO98/35562	08/20/98				+		
	WO00/15194	03/23/00				<u> </u>		
		03/23/00	ÜK					
	1422973	12/07/72				abstract		
4	7212036*	12/07/73	France			abstract		
Υ Ι	7924948**	04/17/81	France			abstract		
RE	WO 00/46147	08/10/00	PCT			-		
			ing Author, Title, Date,					
RZ			it the 1992 meeting or Cold Spring Harbor),			lew Vaccine		
,	Abu-Izza, K.A,	"Effect of gastr	ointestinal protein ad es," Pharm. Dev. Tec	sorption on th	ie in vitro rel			
1	Al-Achi, et al., '	Erythrocytes as	s Oral Delivery Syste	ms for Humai	n Insulin," <i>Di</i>	ug		
\	Development an	d Industrial Ph	armacy, 24(1):67-72	(1998)				
	Aldovini and R.	A. Young, "Hu	moral and cell-media	ated immune i	esponses to l	ive		
1 1			es," Nature 351: 479-					
	Ascadi et al., "F	luman dystroph	in expression in mdx	mice after int	ramuscular ii	ijection of		
	DNA constructs	," <i>Nature</i> 352:	815-818 (1991).					
	Bartus et al., "S	ustained Delive	ry of Proteins for No	vel Therapeut	ic Products,"	Science,		
	281(5380): 116		·					
	Bastin, et al., "L	se of Synthetic	Peptides of Influenza	a Nucleoprote	in to Define	Epitopes		
		•	ed Cytotoxic T Lymp	•				
	1523 (1987).							
	Bayomi, M.A.,		casein-chitosan micro					
RZ		y an aqueous co	pacervation technique					
caminer:	Lema		Date Considered:	Tax				



Sheet 3 of 6 Docket No.: Application No. 09/932,503 Form PTO-1449 37070/207071 Applicant: INFORMATION DISCLOSURE Tulin Morcol, et al. CITATION Group Art Unit IN AN APPLICATION Filing Date: 1645 (Use several sheets if necessary) August 17, 2001 Benvenisty, N., and Reshef, L. "Direct introduction of genes into rats and expression of genes," PNAS 83, 9551-9555, (1986) Bennink and J. W. Yewdell, "Recombinant Vaccinia Viruses as Vectors for Studying Lymphocyte Specificity and Function," Curr. Top. Microbiol. Immunol., 163: 153-184 (1990) Bulgarelli, et al., "Effect of matrix composition and process conditions on casein-gelatin beads floating properties," Int. J. Pharm., 198(2):157-65 (2000). (abstract) Bulgarelli, et al., "Casein/gelatin beads: 1. Cross-linker solution composition effect on crosslinking degree," Int. J. Pharm., 190(2):175-182 (1999). (abstract) Carbone and Bevan, "Induction of Ovalbumin-specific cytotoxic T cells by in vivo peptide immunization," J. Exp. Med., 169(1): 603-612 (1989). Chen, et al., Comparison of albumin and casein microspheres as a carrier for doxorubicin, J. PHARM. PHARMACOL., 39(12):978-85 (1987) Choudhari, et al., Liposomes As a Carrier for Oral Administration of Insulin: Effect of Formulation Factors, 11 (3) JOURNAL OF MICROENCAPSULATION, 319-325 (1994) Collins et al., "Processing of exogenous liposome-encapsulated antigens in vivo generates class I MCH-restricted T cell responses," J. Immunol., 148(11): 3336-3341 (1992). Cooney et al., "Safety of and immunological response to a recombinant vaccinia virus vaccine expressing HIV envelope glycoprotein," Lancet, 337: 567-572 (1991). Cox et al., "Bovine Herpesvirus 1: Immune Responses in Mice and Cattle Injected with Plasmid DNA," 1993, J. Virol., 67(9): 5664-5667. Damge, et al., "New approach for Oral Administration Insulin With Polyalkylcyanoacrylate Nanocapsules as Drug Carrier," Diabetes, 37:246-251 (1988) Damge, et al., "Poly(alkyl cyanoacrylate) Nanospheres for Oral Administration of Insulin," J.Pharm. Sci., 86(12):1403-1409 (1997) Deres, et al., "In vivo priming of virus-specific cytotoxic T lymphocytes with synthetic lipoprotein vaccine," Nature, 342: 561-564 (1989). Donnelly et al., "DNA Vaccines," Annu. Rev. Immunol., 15: 617-648 (1997). Edgington, "Turning On Tumor-Fighting T-Cells," Biotechnology, 11:1117-1119 (1993). Edwards et al., "Large Porous Particles for Pulmonary Drug Delivery," Science, 276:1868-Friedman, T., "Progress toward human gene therapy," Science, 244, 1275-1281 (1989). Furth et al., "Gene Transfer into Somatic Tissues by Jet Injection," Analytical Biochemistry, 205(2): 365-368, (1992). Gardner et al., "Cell-mediated cytotoxicity against ectromelia virus-infected target cells," Eur. J. Immunol., 4: 68-72 (1974). Goto et al., "Local tissue irritating effects and adjuvant activities of calcium phosphate and aluminum hydroxide with different physical properties," Vaccine, 15(12/13):1364-1371 Hahn et al., "Infectious Sindbis virus transient expression vectors for studying antigen processing and presentation," Proc. Natl. Acad. Sci. (USA) 89: 2679-2683 (1992). Hansen et al., "Strong Expression of Foreign Genes Following Direct Injection into Fish RZ Muscle," FEBS Lett. 290, 73-76 (1991). Examiner Date Considered: 3131/04 EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to the applicant.



PADEMATIO-1449	Docket No.: 37070	1/207071	Application No. 09/932,53				
INCORMATION DICCLO		0/2010/1					
INFORMATION DISCLO	SURE Applicant: Tulin	Morcol, et al.	APR H CEN				
IN AN APPLICATION			Group Art Unit				
(Use several sheets if nec			1045 30 -1				
OTHE	R DOCUMENTS (Includia	ng Author, Title, Date, Pertinen	t Pages, Etc.) I agents from sodium sinates				
Hee	lan, et al., "In vitro analysis	of the release of incorporated	agents from sodium casellates				
micr	ospheres," J. Microencapsi	d., 14(1):63-78 (1997). (abst	ract)				
coat	ed capsules containing sodic tract)	um cholate," Pharm. Acta. He					
Hos	ny, "Hypoglycemic Effect C	of Oral Insulin in Diabetic Ra	bbits Using pH-Dependent				
Coa	ted Capsules Containing So	dium Salicylate Without And	With Sodium Cholate," 24(3)				
DRU	G DEVELOPMENT AND INDUS	STRIAL PHARMACY 24(3):307-3	dia tion Consoits of Aluminum				
Kato	et al., "Relationship betwe	en Hemolytic Activity and A	dsorption Capacity of Aluminum				
			ants for Biologicals," Microbiol.				
Imm	unol., 38(7): 543-548 (1994	ion of Inculin as Poly(Viny)	Alcohol)-Gel Spheres in Diabetic				
		TIN, 19(6):897-900 (1996). (
Kite	is et al. "Hormonal modula	tion of a gene injected into ra	t heart in vivo." Proc. Natl.				
	Kitsis et al., "Hormonal modulation of a gene injected into rat heart in vivo," Proc. Natl. Acad. Sci. (USA) 88: 4138-4142 (1991).						
Kne	pp. "Synthesis, properties, a	nd intratumoral evaluation of	f mitoxantrone-loaded casein				
mici	ospheres in Lewis lung caci	imnoma, " 45(10) <i>J. PHARM. I</i>	PHARMACOL, 887-91 (1993).				
(abs	(abstract)						
Lath	a, "Progesterone release fro	esterone release from glutaraldehyde cross-linked casein microspheres: in vitro					
stud	ies and in vivo response in t	raldehyde cross-linked bovine casein microspheres as a matrix for the controlled					
Lath	a, "Glutaraldehyde cross-lin	nked bovine casein microsphe	eres as a matrix for the controlled				
	- · · ·	studie," 46(1) J. PHARM. PH.	ARMACOL, 8-13 (1994).				
(abs	tract)		mig release from migrospheres				
drug	Latha, et al., "Casein as a carrier matrix for 5- fluorouracil: drug release from microspheres, drug-protein conjugates and in-vivo degradation microspheres in rat muscle," 46(11) J. PHARM. PHARMACOL, 858-62 (1994)						
Lath	Latha, et al., "A new method for the synthesis of smooth, round, hydrophilic protein						
	microspheres using low concentrations of polymeric dispersing agents," J. Microencapsl., 12(1):7-12 (1995). (abstract)						
of C	NA," Circulation 82(6): 22	17-2221 (1990).	m In Vivo after Direct Injection				
Lin	and Askonas, "Biological p	roperties of an influenza A vi	rus-specific killer T cell clone,"				
J. E.	xp. Med. 154(1): 225-234 (1981).					
		ulin Using pH-Responsive Co	omplexation Gels," 88(9)				
Jou	RNAL OF PHARMACEUTICAL S	SCIENCES, 933-937 (1999)	.00				
Mar	niatis, et al., "Molecular Clo	ning, A laboratory Manuel, 2	end Edition," Cold Spring Harbor				
Lab	oratory Press, New York, 1.	U - 19.U (1989). *	ounty 1005 1006" Arch Inform				
Med Med	I., 149(7): 1569-1572 (1989	·).	ounty, 1985-1986," Arch. Intern.				
KE / 176	Michael et al., "Cytotoxic T 1983).		New Engl. J. Med., 309(1): 13-				
Examiner /	ma	Date Considered:	C COO. Danielling through disables if				
EXAMÍNER: Initial if citation of not in conformance and not co	considered, whether or not citationsidered. Include copy of this	ion is in conformance with MPEP form with next communication to	§ 609; Draw line through citation if the applicant.				



Sheet 5 of 6

	TRADEMAN	Docket No.:	Application No.
Form PTO-	1449	37070/207071	Application No. 09/932,53
		Applicant:	i A
INFOR	RMATION DISCLOSURE CITATION	Tulin Morcol, et al.	APR 1 CEN
IN	AN APPLICATION	Filing Date:	Group Art Unit
	veral sheets if necessary)	August 17, 2001	1645
		MENTS (Including Author, Title, Date, Per	
00		al., "Recognition of Influenza A virus Nu	
12	lymphocytes,"	J. Gen. Virol., 67: 719-726 (1986).	29
	Michel, et al., '	The Effect of Site of Administration in t	he Gastrointestinal Tract on the
		Insulin from Nanocapsules in Diabetic Ra	ats," J. Pharm. Pharmacol., 43:1-5
	(1991)		2 4 4 2 2 2 2
	Miller, "Retrov	riral Vectors," Curr. Top. Microbiol. Imn	nunol.,158, 3-24 (1992).
	Musabayane, e	t al., Orally administered, insulin-loaded	amidated pectin hydogel beads
		concentrations of insulin in streptozotoci	n-diabetic rats, 164(1) JOURNAL OF
	ENDOCRINOLOG	7Y, 1-6 (2000)	
		Comparison of the mechanism of dissolu	
	mixed micelle	systems, "Pharm. Res. 10(6):865-70 (19	3). (abstract)
	Olivares, et al.	Effects of a Protective Hydrolized Case	In Diet Opon the Metabolic and
	Secretory Resp	onses of Pancreatic Islets to IL-1β, Cyto itogenic and Biosynthetic Activities and	Payers' Patch Cells, and Mitogenic
	Node Cells, M	ancreatic Lymph Node Cells from Control	l and Diabetes-Prone RR Rats 68(3)
		ENETICS AND METABOLISM 379-390 (1999	
	Redfield et al	"Disseminated Vaccinia in a Military Re	cruit with Human Immunodeficiency
	Virus (HIV) D	isease," New Engl. J. Med., 316(11): 673	-676 (1987).
	Robinson et al.	, "Protection against a lethal influenza vi	rus challenge by immunization with a
	haemagglutinir	n-expressing plasmid DNA," Vaccine 11	9): 957-960 (1993).
		, "The stability of liposome's in vitro to	pH, bile salts and pancreatic lipase,"
	Biochem. Biop	hsy. Acta., 620(3):400-9 (1980)	hamical proportion of casein
	Santinho, et al.	, Influence of formulation on the physico 186(2) INTL. JOURNAL OF PHARMACEUTI	CS, 191-98 (1999)
	Sato et al., "Im	munostimulatory DNA Sequences Neces	sary for Effective Intradermal Gene
	Immunization,	" Science 273: 352-354 (1996).	
	Schafer et al.,	'Induction of a cellular immune response	to a foreign antigen by a recombinant
	Listeria monoc	cytogenes vaccine," J. Immunol., 149(1):	53-59 (1992).
	Stover et al., "	New use of BCG for recombinant vaccin	es," Nature 351: 456-460 (1991).
		., "Induction of CD8 cytotoxic T cells by	
	envelope prote	in in ISCOMs," Nature, 344: 873-875 (1	990).
		enetic immunization is a simple method	for eliciting an immune response,"
1	Nature, 356: 1	52-154 (1992).	
K2		konas, "Influenza nucleoprotein-specific nol., 58(1): 417-420 (1986).	cytotoxic 1-cell clones are protective
Examiner/	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	Date Considered:	
Ka	Let teman	3/3//04	
EXAMINER	: Initial if citation considered,	whether or not citation is in conformance with	MPEP § 609; Draw line through citation if



	PATE TRADEMAN		Sheet 6 of 6
	TRADEMA		
		Docket No.:	Application No.
	Form PTO-1449	37070/207071 Applicant:	09/932,503 C A
INFO	RMATION DISCLOSURE CITATION	Tulin Morcol, et al.	09/932,503 C A
1	N AN APPLICATION	Filing Date:	Group Art Unit
(USE S	everal sheets if necessary)	August 17, 2001	1645
P2			Group Art Unit 1645 T lymphocytes," Annu. Rev. Infimunol S
	Lymphocytes (., "The Epitopes of Infulenza Nucleop Can Be Defined with Short Synthetic P	eptides," Cell 44: 959-968 (1986).
		Chitosan Capsules for Colon-Specific m the Rat Colon," <i>J. Pharm. Sci.</i> , 86(9)	Drug Delivery: Improvement of Insulin):1016-1021 (1997)
		Oral administration of insulin by means with Wochenschr, 91(13):448-	of liposome's in animal experiments" 51 (1979)
	Ulmer, J. B. et	al., "Heterologous Protection Against al Protein," Science, 259: 1745-1749 (Influenza by Injection of DNA
	Wang et al., "C		ponses against human immunodeficiency
	Wang, et al., "I		hepatitis B DNA vaccine by formulation
 		Immunostimulatory oligodeoxynucleo	
			nization," <i>PNAS (USA)</i> 94(19): 10833-
	Willmott, et al.	"Biodegradation rate of embolized pr J. Pharm. Pharmacol., 41(7):433-438	
	Willmott, et al.	Doxorubicin-loaded casein microsph 14(6) J. PHARM. PHARACOL, 472-75 (1	eres: protein nature of drug
	Wolff et al., "L		and foreign gene expression in mouse
		Direct Gene Transfer into Mouse Musc	le in Vivo," Science 247: 1465-1468
	Yap and Ada, "	Transfer of specific cytotoxic T lymph "Nature, 273: 238-239 (1978).	nocytes protects mice inoculated with
	Yewdell et al.,	"Influenza A virus nucleoprotein is a n	najor target antigen for cross-reactive c. Natl. Acad. Sci. (USA) 82: 1785-1789
		temic Gene Expression After Intravend	ous DNA Delivery into Adult Mice,"
RZ	http://vaxa.com		
	2/10		
Examiner:	That fem	Date Considered:	
EXAMINER not in confo	: Initial if citation considered, w rmance and not considered. In	hether or not citation is in conformance wit clude copy of this form with next communic	h MPEP § 609; Draw line through citation if cation to the applicant.



PTO/SB/08A (10-01)

Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Ibstitute for form 1449A/PTO

Complete if Known 09/932,503 Application Number August 17, 2001 Filing Date Tulin MORCOL First Named Inventor 1645 Group Art Unit **Examiner Name** Attorney Docket Number 37070/207071

(use as many sheets as necessary) of 2 Sheet

			U.S. PATENT	OCUMENTS	
F	Cita	Document Number	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant
Examiner Initials *	Cite No.'	Number - Kind Code ² (If known)	MM-DD-YYYY	Onco bossinoni	Passages or Relevant Figures Appear
PE		3,382,150	05/07/1968	Grass, et al.	
et		4,929,774	05/29/1990	Fukamachi, et al.	
R		6,024,987	02/15/2000	Jettka, et al.	
	<u> </u>				

		FOREIGN PA	TENT DOCUM	ENTS		
Examiner Initials*	Cite No.1	Foreign Patent Document Country Code ³ - Number ⁴ - Kind Code ⁵ (<i>il known</i>)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Τ.
1E		EP 0 715 846 A	06/12/1996	Europe		
		EP 0 326 026 A	08/02/1989	Europe		
	 					

Examiner Signature	Kohut	tena	Date Considered	3 31 04

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

PTO/SB/08B(10-01)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

TRANStitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary) Sheet

	Complete if Known	\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \
Application Number	09/932,503	
Filing Date	August 17, 2001	
First Named Inventor	Tulin MORCOL	
Group Art Unit	1645	
Examiner Name		
Attorney Docket Number	37070/207071	

		OTHER PRIOR ART NON PATENT LITERATURE DOCUMENTS	· · · · · ·
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T 2
		International Search Report issued in related Application No. PCT/US02/03506	
		Patent Abstracts of Japan & JP 09 208491 A (Ashai Optical) 12 August 1997	
		·	
		·	
···			
			-
			-

Examiner Signature	lohnt time	Date Considered	3/3/04	

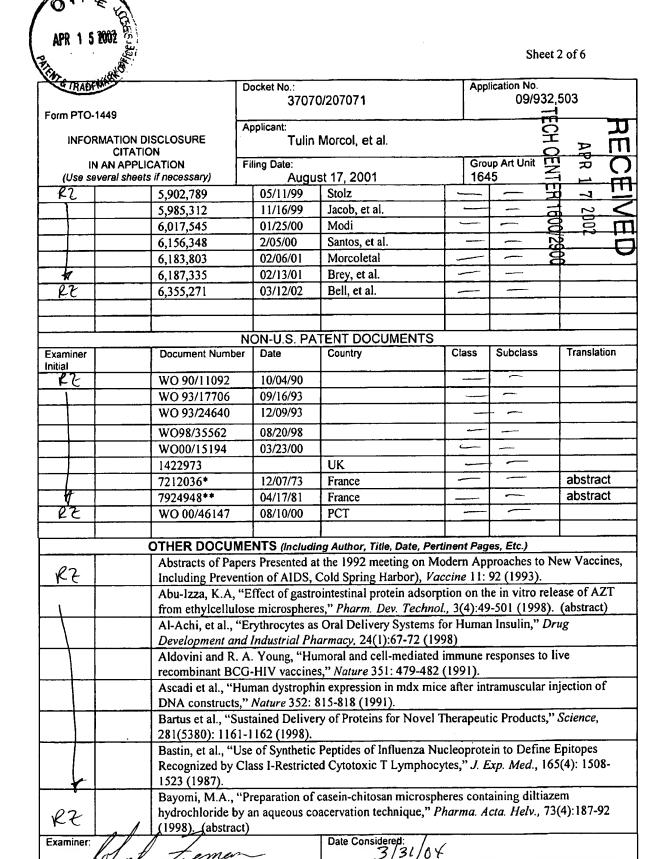
EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



Sheet 1 of 6

Form PYO 1440		Doc	ket No.: 3707	0/207071	Apı	olication No. 09/932	,503 声	_
orm PTO-1449)	Ana	licant:			- 		
INFORMATION DISCLOSURE CITATION IN AN APPLICATION		Арр		Morcol, et al.			CENTER	
		Filin	g Date:			oup Art Unit	LI III	-
(Use severe	al sheets if necessary)	<u> </u>		st 17, 2001	16	45	$\stackrel{\sim}{\Rightarrow}$	
				NT DOCUMENTS			8	7
xaminer nitial	Document Numb		Date	Name	Class	Subclass	Translati	iop —
RZ	3,925,545		12/09/75	Relyveld			8	
4	4,016,252		04/05/97	Relyveld				
	4,350,686		09/21/82	Relyveld, et al.				
	4,500,512	1	02/19/85	Barme			Ī	
	4,552,756		11/12/85	Relyveld, et al.				
	4,963,526		10/16/90	Ecanow	~_			
1 1	5,110,606	_	05/05/92	Geyer, et. al				
	5,178,882		01/12/93	Kossovsky et al.				
	5,219,577	$\overline{}$	06/15/93	Kossovsky et al.				
	5,306,508		04/26/94	Kossovsky et al.				_
	5,334,394	$\overline{}$	08/02/94	Kossovsky et al.			<u> </u>	_
	5,364,838	_	11/15/94	Rubsamen				
	5,428,066	_	06/27/95	Larner, et al.			<u> </u>	
	5,460,830		10/24/95	Kossovsky et al.			 	
· -	5,460,831		10/24/95	Kossovsky et al.		<u> </u>		
+	5,462,750		10/24/95	Kossovsky et al.				_
	5,462,751		10/31/95	Kossovsky et al.			<u> </u>	-
	5,464,634		11/07/95	Kossovsky et al.	+=	-		_
+ +			04/09/96	Backstrom et al.		<u> </u>		-
	5,506,203		08/27/96	Majetich et al.			 	
	5,549,973						<u> </u>	
	5,580,859		12/03/96	Felgner et al.		Ī		
	5,593,875		01/14/97	Wurm, et al.			<u> </u>	
	5,595,762		1/21/97	Derrieu et al.	1		 	_
	5,618,800		04/08/97	Kabra, et al.			ļ	
	5,620,896		04/15/97	Herrmann et al.			ļ	
	5,629,021		05/13/97	Wright				
	5,641,515		06/24/97	Ramtoola	-		ļ	
	5,648,097		7/15/97	Nuwayser				
	5,665,382		09/09/97	Grinstaff, et al.			<u> </u>	_
	5,695,617		12/09/97	Gravier et al.				
	5,747,001		05/05/98	Wiedmann et al.				
	5,785,975	(07/28/98	Parikh				
	5,824,638		10/20/98	Burnside, et al.				
	5,827,822	[]	10/27/98	Floc'h et al.				
	5,843,887		12/01/98	Petit, et al.				
	5,858,398		01/12/99	Cho				
	5,866,553		02/02/99	Donnelly et al.	T	 		
₩	5,891,420		04/06/99	Cutie				
RZ	5,898,028		04/27/99	Jensen et al.				_

not in conformance and not considered. Include copy of this form with next communication to the applicant.



EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609; Draw line through citation if

not in conformance and not considered. Include copy of this form with next communication to the applicant.



		Sheet 3 of 6
Distriction	Docket No.: 37070/207071 Applicant: Tulin Morcol, et al. Filing Date: August 17, 2001 y, N., and Reshef, L. "Direct introduction of NAS 83, 9551-9555 (1986)	Application No.
Form PTO-1449	37070/207071	09/932,503 EN 7
INFORMATION DISCLOSURE	Applicant:	¥ ;
CITATION	Tuliit Morcol, et al.	<u></u>
IN AN APPLICATION	Filing Date:	Group Art Unit
(Use several sheets if necessar	9 August 17, 2001	f genes into rats and expression of
Benvenis	y, N., and Reshef, L. "Direct introduction of	f genes into rats and expression 🗨 🛛 🗧
1 1 20103. 1	(1/1D OJ. /JJ 1-/JJJ. (1/OU)	•
Bennink	and J. W. Yewdell, "Recombinant Vaccinia	Viruses as Vectors for Studying
Lymphoc	yte Specificity and Function," Curr. Top. Mi	icrobiol. Immunol., 163: 153-184 (1990)
Bulgarell	, et al., "Effect of matrix composition and pr	rocess conditions on casein-gelatin
beads flo	ting properties," Int. J. Pharm., 198(2):157	-65 (2000). (abstract)
	, et al., "Casein/gelatin beads: I. Cross-linke	
linking de	gree," Int. J. Pharm., 190(2):175-182 (1999)	9). (abstract)
	nd Bevan, "Induction of Ovalbumin-specifi	
immuniza	tion," J. Exp. Med., 169(1): 603-612 (1989)	<u> </u>
	I., Comparison of albumin and casein micro	spheres as a carrier for doxorubicin,
J. PHARM	РНАКМАСОЬ., 39(12):978-85 (1987)	
	i, et al., Liposomes As a Carrier for Oral Ad	
Formulat	on Factors, 11 (3) JOURNAL OF MICROENCAF	PSULATION, 319-325 (1994)
	al., "Processing of exogenous liposome-enc	
	CH-restricted T cell responses," J. Immunol.	
	t al., "Safety of and immunological response	
expressin	g HIV envelope glycoprotein," <i>Lancet</i> , 337:	50/-5/2 (1991).
	, "Bovine Herpesvirus 1: Immune Response	es in Mice and Cattle injected with
Plasmid	DNA," 1993, J. Virol., 67(9): 5664-5667. t al., "New approach for Oral Administration	n Inculin With Polyalbylovanoacrylate
	ules as Drug Carrier," Diabetes, 37:246-251	
	t al., "Poly(alkyl cyanoacrylate) Nanosphere	
	Sci., 86(12):1403-1409 (1997)	s for Oral Administration of msami,
	al., "In vivo priming of virus-specific cytoto:	vic T lymphocytes with synthetic
	n vaccine," <i>Nature</i> , 342: 561-564 (1989).	Alo I lymphobytes with symmetre
Donnelly	et al., "DNA Vaccines," Annu. Rev. Immuno	ol. 15: 617-648 (1997).
Edgingto	n, "Turning On Tumor-Fighting T-Cells," Bi	iotechnology, 11:1117-1119 (1993).
Edwards	et al., "Large Porous Particles for Pulmonary	v Drug Delivery." Science, 276:1868-
1871 (19		,,,,
	T., "Progress toward human gene therapy,"	Science, 244, 1275-1281 (1989).
	I., "Gene Transfer into Somatic Tissues by J	
	65-368, (1992).	
	et al., "Cell-mediated cytotoxicity against ect	tromelia virus-infected target cells," Eur.
1 1 1	ol., 4: 68-72 (1974).	-
	., "Local tissue irritating effects and adjuvar	at activities of calcium phosphate and
	hydroxide with different physical properties	
(1997).	a.	-,
	l., "Infectious Sindbis virus transient express	sion vectors for studying antigen
	g and presentation," Proc. Natl. Acad. Sci. (
Uancan a	al., "Strong Expression of Foreign Genes F	ollowing Direct Injection into Fish
	FEBS Lett. 290, 73-76 (1991).	
Examiner://	Date Considered:	
Kohnt Len	a 3/31/04	
EXAMINER: Initial if citation consid	ered, whether or not citation is in conformance with	h MPEP § 609; Draw line through citation if
not in conformance and not conside	ed. Include copy of this form with next communic	зации то тне аррисант.



Application No. Docket No.: 09/932.53 37070/207071 Applicant: INFORMATION DISCLOSURE Tulin Morcol, et al. CITATION Filing Date: **Group Art Unit** IN AN APPLICATION (Use several sheets if necessary) August 17, 2001 1645 OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) Heelan, et al., "In vitro analysis of the release of incorporated agents from sodium caseinates RZ microspheres," J. Microencapsul., 14(1):63-78 (1997). (abstract) Hosny, et al, "Promotion of oral insulin adsorption in diabetic rabbits using pH-dependent coated capsules containing sodium cholate," Pharm. Acta. Helv., 72(4):203-7 (1997). Hosny, "Hypoglycemic Effect Of Oral Insulin in Diabetic Rabbits Using pH-Dependent Coated Capsules Containing Sodium Salicylate Without And With Sodium Cholate," 24(3) DRUG DEVELOPMENT AND INDUSTRIAL PHARMACY 24(3):307-311 (1998) Kato et al., "Relationship between Hemolytic Activity and Adsorption Capacity of Aluminum Hydroxide and Calcium Phosphate as Immunological Adjuvants for Biologicals," Microbiol. Immunol., 38(7): 543-548 (1994). Kimura, et al., Oral Administration of Insulin as Poly(Vinyl Alcohol)-Gel Spheres in Diabetic Rats, 19(6) BIOL. PHARM. BULLETIN, 19(6):897-900 (1996). (abstract) Kitsis et al., "Hormonal modulation of a gene injected into rat heart in vivo," Proc. Natl. Acad. Sci. (USA) 88: 4138-4142 (1991). Knepp, "Synthesis, properties, and intratumoral evaluation of mitoxantrone-loaded casein microspheres in Lewis lung cacimnoma, "45(10) J. PHARM. PHARMACOL, 887-91 (1993). (abstract) Latha, "Progesterone release from glutaraldehyde cross-linked casein microspheres: in vitro studies and in vivo response in rabbits, "61(5) CONTRACEPTION, 329-34 (2000). (abstract) Latha, "Glutaraldehyde cross-linked bovine casein microspheres as a matrix for the controlled release of theophylline: in0vitro studie," 46(1) J. PHARM. PHARMACOL, 8-13 (1994). (abstract) Latha, et al., "Casein as a carrier matrix for 5- fluorouracil: drug release from microspheres, drug-protein conjugates and in-vivo degradation microspheres in rat muscle," 46(11) J. PHARM. PHARMACOL, 858-62 (1994) Latha, et al., "A new method for the synthesis of smooth, round, hydrophilic protein microspheres using low concentrations of polymeric dispersing agents," J. Microencapsl., 12(1):7-12 (1995). (abstract) Lin et al., "Expression of Recombinant Genes in Myocardium In Vivo after Direct Injection of DNA," Circulation 82(6): 2217-2221 (1990). Lin and Askonas, "Biological properties of an influenza A virus-specific killer T cell clone," J. Exp. Med. 154(1): 225-234 (1981). Lowman, "Oral Delivery of Insulin Using pH-Responsive Complexation Gels," 88(9) JOURNAL OF PHARMACEUTICAL SCIENCES, 933-937 (1999) Maniatis, et al., "Molecular Cloning, A laboratory Manuel, 2nd Edition," Cold Spring Harbor Laboratory Press, New York, 1.0 - 19.0 (1989). * Mascola et al., "Surveillance of Listeriosis in Los Angeles County, 1985-1986," Arch. Intern. Med., 149(7): 1569-1572 (1989). McMichael et al., "Cytotoxic T-Cell Immunity to Influenza," New Engl. J. Med., 309(1): 13-R2 17 (1983). Date Considered Examiner EXAMÍNER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to the applicant.



Sheet 5 of 6

XCA.						
Form PTO-1449	ADFIAN	Docket No.:	/207071	Application No. 09/932,53	EC SE	
100000		Applicant:	7201011	00/002 00	1	75
INFORMATION DI		Tulin N	Morcol, et al.		CE CE	APR
IN AN APPLIC	CATION	Filing Date:		Group Art Unit	TER	1
(Use several sheets	if necessary)	August 17, 200	01	1645		~
	OTHER DOCU	MENTS (Includin	g Author, Title, Date, Pertine of Influenza A virus Nucleo	nt Pages, Etc.)	- 6	2002
12	McMichael et a	al., "Recognition of J. Gen. Virol., 67	of Influenza A virus Nucleo ; 719-726 (1986).	protein by human cyto	NOXES	02
	Michel et al	The Effect of Site	e of Administration in the C	astrointestinal Tract of	n the	
	Absorption of l	Insulin from Nanc	capsules in Diabetic Rats,"	J. Pharm. Pharmacol	!., 43:1-:	5
	(1991)		•			
	Miller, "Retroy	iral Vectors," Cu	rr. Top. Microbiol. Immuno	ol.,158, 3-24 (1992).		
	Musabayane, e	t al Orally admir	nistered, insulin-loaded ami	dated pectin hydogel b	eads	
	sustain plasma	concentrations of	insulin in streptozotocin-di	iabetic rats, 164(1) Joe	URNAL O	F
	ENDOCRINOLOG		•			
 	Navlor, et al., '	Comparison of th	ne mechanism of dissolution	of hydrocortisone in	simple a	ınd
	mixed micelle	systems, " Pharm	. Res. 10(6):865-70 (193).	(abstract)		
	Olivares, et al.,	Effects of a Prote	ective Hydrolized Casein D	iet Upon the Metaboli	c and	
	Secretory Resp	onses of Pancreat	tic Islets to IL-1B, Cytokine	Production by Mesen	teric Ly	mph
	Node Cells, M	itogenic and Bios	ynthetic Activities and Peye	ers' Patch Cells, and M	litogenic	:
	Activity and Pa	ancreatic Lymph 1	Node Cells from Control an	d Diabetes-Prone BB	Rats, 68	.(3)
	MOLECULAR GI	ENETICS AND META	4BOLISM 379-390 (1999)			
	Redfield et al.,	"Disseminated V	accinia in a Military Recrui	it with Human Immuno	odeficier	ncy
	Virus (HIV) D	isease," New Eng	l. J. Med., 316(11): 673-67	6 (1987).		
	Robinson et al.	, "Protection agai	nst a lethal influenza virus	challenge by immuniza	ation wit	th a
	haemagglutinir	n-expressing plasm	nid DNA," Vaccine 11(9):	957-960 (1993)		
			f liposome's in vitro to pH,	bile salts and pancreat	ic lipase	<i>;</i> ,"
	Biochem. Biop	hsy. Acta., 620(3)	:400-9 (1980)			
	Santinho, et al.	, Influence of for	mulation on the physiochen	nical properties of case	in	
	microparticles,	186(2) INTL. JOU	IRNAL OF PHARMACEUTICS,	191-98 (1999)		
			DNA Sequences Necessary	for Effective Intrader	mal Ger	16
	Immunization,	" Science 273: 35	2-354 (1996).	C 1 11 1		
			Ilular immune response to a		recombi	nant
			," J. Immunol., 149(1):53-5		(1001)	
	Stover et al., "	New use of BCG	for recombinant vaccines,"	Nature 331: 430-400	(1991).	-
	Takahashi et a	i., "Induction of C	D8 cytotoxic T cells by im	munization with purifi	cu m v-	-1
	envelope prote	in in iscovis, A	Vature, 344: 873-875 (1990). Vigiting on immung res	enonce "	,
	Nature, 356: 1		ion is a simple method for e	menting an infinition res	sponse,	
	Taylor and Asi	conas, "Influenza	nucleoprotein-specific cyto	toxic T-cell clones are	protect	ive
K2 ,		nol., 58(1): 417-4			•	
Examiner			Date Considered:			
EXAMINER: Initial if cit	tation considered, v	whether or not citation	on is in conformance with MPE	P § 609; Draw line throug	gh citation	n if
not in conformance and	not considered. In	nclude copy of this f	form with next communication t	to the applicant.		



,	(F)	TO TRADEMINE				Sheet 6	of 6	
		GIRAUT	Docket	No.:		Application No.	2	
	For	m PTO-1449		37070/207071		09/932,5	03 🖸	APR
INFO	RMATION DI	ISCLOSURE ON	Applica	nt: Tulin Morcol, et al			NTE	
	N AN APPLI	CATION	Filing D		· 	Group Art Unit		
(Use s	overal sneets	s if necessary)	<u> </u>	August 17, 2001	4 1 4 1 77 1	1645	-8 -	200
RZ				August 17, 2001 cognition by class I-re				<i>01</i> 555
				epitopes of Infulenza Nefined with Short Syn				
		Tozak, et al., "(Chitosan	Capsules for Colon-S t Colon," J. Pharm. So	pecific Drug D	elivery: Improvemen		lin
	-	Tragl, et al., "O	ral admi	nistration of insulin by	y means of lipo	some's in animal exp	eriment	s"
 	<u> </u>			Llin Wochenschr, 91(1 erologous Protection A			ĪA	
<u> </u>		Encoding a Vir	al Protei	n," <i>Science</i> , 259: 1745	5-1749 (1993).			
				ulation generates imm JSA 90: 4156-4160 (N		against human immu	nodefici	ency
		Wang, et al., "E	nhanced	I type I immune respor um phosphate," Vacci	nse to a hepatiti		formula	ation
 				stimulatory oligodeoxy			tif are	
				uvants in tumor antige				33-
	 _	Willmott, et al.,		gradation rate of embo m. Pharmacol., 41(7):			liver and	i
		Willmott, et al.,	Doxoru	bicin-loaded casein m	icrospheres: pr			
				PHARM. PHARACOL, 47				
		muscle," Huma	n Mol. C	persistence of plasmi Genet. 1(6): 363-369 (1	1992).			
		Wolff et al., "D (1990).	irect Ge	ne Transfer into Mous	e Muscle in Vi	vo," Science 247: 14	65-1468	;
				of specific cytotoxic , 273: 238-239 (1978)		protects mice inocula	ated with	1
	<u> </u>	Yewdell et al., '	'Influenz	za A virus nucleoprote	in is a major ta			
		anti-influenza A (1985).	virus cy	totoxic T lymphocyte	s," Proc. Natl.	Acad, Sci. (USA) 82	: 1785-1	.789
1		Zhu et al., "Syst Science 261: 20		ene Expression After In	ntravenous DN	A Delivery into Adu	t Mice,"	,
RZ		http://vaxa.com						
								
	1	1 -						
Examiner:	11	1.		Date Considered:				
EXAMINER	: Initial if cit	atton considered, w	hether or	not citation is in conform	ance with MPEP	§ 609; Draw line through	h citation	ı if
not in confo	rmance and	not considered. In	clude cop	y of this form with next co	ommunication to	the applicant.		



PTO/SB/08A (10-01)

Approved for use through 10/31/2002. OMB 0651-0031 U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

stitute for form 1449A/PTO

 Complete if Known

 Application Number
 09/932,503

 Filing Date
 August 17, 2001

 First Named Inventor
 Tulin MORCOL

 Group Art Unit
 1645

 Examiner Name
 37070/207071

(use as many sheets as necessary)

Sheet 1 of 2

			U.S. PATENT	OCUMENTS	
Examiner Cite No.'	Document Number	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	
	Number - Kind Code ² (if known)	MM-DD-YYYY	Once bosinon		
pe		3,382,150	05/07/1968	Grass, et al.	
et		4,929,774	05/29/1990	Fukamachi, et al.	
R		6,024,987	02/15/2000	Jettka, et al.	
					8
-	 	+			
	 				
	1				

		FOREIGN PA	TENT DOCUM	ENTS		
Examiner Initials*	Cite No.1	Foreign Patent Document Country Code ³ - Number ⁴ - Kind Code ⁵ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant	T ⁶
RE		EP 0 715 846 A	06/12/1996	Europe	Figures Appear	
		EP 0 326 026 A	08/02/1989	Europe		
	 -					
	 					

Examiner Signature	Kohnt	Lema	Date Considered	3/31/04	

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

PTO/SB/08B(10-01)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

TRANSitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Complete if Known Application Number 09/932,503 August 17, 2001 Filing Date First Named Inventor Tulin MORCOL 1645 Group Art Unit **Examiner Name** 37070/207071 Attorney Docket Number

(use as many sheets as necessary) of 2 Sheet

OTHER PRIOR ART NON PATENT LITERATURE DOCUMENTS							
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.					
		International Search Report issued in related Application No. PCT/US02/03506					
		Patent Abstracts of Japan & JP 09 208491 A (Ashai Optical) 12 August 1997					
		*					

Date Examiner Considered Signature

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.